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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,458	08/13/2001	David Wallach	WALLACH=22A	6865

7590 04/05/2002

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 04/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,458

Applicant(s)

WALLACH ET AL.

Examiner

Richard Schnizer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 17, 21-23, 26, and 27, drawn to nucleic acids encoding a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity, classified in class 536, subclass 23.5.
- II. Claims 10-12, 24, drawn to antisense nucleic acids and methods of use methods of , classified in class 536, subclass 24.1.
- III. Claims 13-16, drawn to a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity, classified in class 530, subclass 350.
- IV. Claims 18 and 19, drawn to antibodies, classified in class 530, subclass 387.1.
- V. Claims 20, 26 and 27, drawn to methods of modulating RIP-modulated effects by administering a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity, classified in class 435, subclass 183.
- VI. Claim 25, drawn to methods of making polypeptides capable of binding to RIP and modulating or mediating its intracellular activity, classified in class 435, subclass 69.1.

- VII. Claim 27, drawn to methods of modulating RIP-modulated effects by administering a nucleic acid encoding a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity, classified in class 435, subclass 455.

Claim 27 is generic to a plurality of patentably distinct species listed as groups I and VII. Should Applicant elect either of these groups, claim 27 will be examined to the extent that it is defined by the classification of the elected group.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of group I are related to the antisense polynucleotides of group II because the antisense polynucleotides are derived from the polynucleotides of group I. The inventions are distinct because the antisense polynucleotides cannot be used for the same purposes as the polynucleotides of group I. For example, the antisense polynucleotides cannot be used for the production of protein. Further the polynucleotides of group I, as claimed, cannot be used as antisense inhibitors of gene expression, as is intended for the polynucleotides of group II.

The polynucleotides of group I are related to the polypeptides of group III and the methods of groups V-VII because the polynucleotides encode the polypeptides, and could therefore be used in these methods. The polynucleotides have utility for the recombinant production of the protein in a host cell. Although the polynucleotides and the polypeptides are related, since the polynucleotides encode the specifically claimed polypeptides, they are distinct inventions because the polypeptide products can be made by other and materially distinct processes, such as purification from natural

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sources. Further, polynucleotides can be used for processes other than the methods of groups V-VII, such as nucleic acid hybridization assays.

The polynucleotides of group I and the antibodies of group IV are related because the polynucleotides encode the cognate antigens of the antibodies. However, the polynucleotides are not directly necessary for antibody production, and the polynucleotides and antibodies are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The antisense polynucleotides of group II are unrelated to the polypeptides of group III, to the antibodies of group IV, or to the methods of groups V-VII. The antisense polynucleotides are distinct in structure and function from the polypeptides and antibodies, and cannot be made by, or used in, the methods of groups V-VII.

The polypeptides of group III are related to the antibodies of group IV because the polypeptides can be used for the production of the antibodies. The polypeptides are a distinct invention because they can be used in other processes which are materially different from the production of antibodies. For example, the polypeptides can be used modulate RIP-mediated processes. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

The polypeptides of group III are related to the method of group V as a product and a method of use. These inventions are distinct because the polypeptides can be used for unrelated methods such as the production of antibodies.

The polypeptides of group III are related to the methods of groups VI and VII as a product and a methods of making the product. The inventions are distinct because

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the product can be made by other unrelated means such as synthetic organic chemistry or purification from a natural source.

The antibodies of group IV are unrelated to the methods of groups V-VII. The antibodies are not disclosed as capable of use in these methods, and the methods do not result in the production of the antibodies.

The methods of groups V-VII are related to the extent that they involve the production of a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity. They are distinct because they employ different reagents, and have different method steps. For example, the methods of claims V and VII lead to the same outcome, but require administration of different chemical entities (nucleic acids vs polypeptides) with different functions and effects. The method of claim VI does not lead to the modulation of RIP activity, as do the methods of groups V and VII, requires different nucleic acids than those required for group VII.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 103-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

A handwritten signature in black ink, appearing to read 'R. Schnizer', with a horizontal line extending from the end.

Richard Schnizer, Ph.D.